

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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SERIAL NUMBER FILING DATE	FIRST NAMED	INVENTO	DR	ATTORNEY DOCKET NO.
07/895.964 02/20/92 0	DOATES			LAF-14 EXAMINER
	12M2/0520	3	TSANG, C	
JAMES F. HALEY, JR.		-	ART UNIT	PAPER NUMBER
FISH & NEAVE 1251 AVENUE OF THE AMERIC	:AS			15
SOTH FLOOR NEW YORK, NY 10020			1202	
is is a communication from the examiner in charge	of your application.		DATE MAILED:	05/23/94
OMMISSIONER OF PATENTS AND TRADEMAŘKS	\$ ''			
This application has been examined Rea	sponsive to communic	ation filed	on 3/15/44	This action is made fina
shortened statutory period for response to this action	n is set to expire	<u>3</u> m	onth(s), days fr	om the date of this letter.
illure to respond within the period for response will o			abandoned. 35 U.S.C. 133	
Int I THE FOLLOWING ATTACHMENT(8) ARE P	ART OF THIS ACTIO	N:		
Notice of References Cited by Examiner, P Notice of Art Cited by Applicant, PTO-1448 Information on How to Effect Drawing Char	. 2 shorts		Notice of Draftsman's Pa Notice of Informal Patent	atent Drawing Review, PTO-948 Application, PTO-152.
et II SUMMARY OF ACTION				
1 Clastres 3 - 5 7 10	al and	22		are sanding in the application
7	<u> </u>			are pending in the application
Of the above, claims			area	withdrawn from consideration.
. Claims 1, 2, 6, 8, 9, 1				
, Claims				_ are allowed.
. ♥ Claims 3-5, 7, 10, 3				
. Claims				_ are objected to.
. Claims			are subject to restriction	on or election requirement.
. This application has been filed with informal d	rawings under 37 C.F.	.R. 1.85 wi	nich are acceptable for exam	Ination purposes.
. Tormal drawings are required in response to t	his Office action.			
The corrected or substitute drawings have been are acceptable; I not acceptable (see exp				C.F.R. 1.84 these drawings TO-948).
The proposed additional or substitute sheet(s examiner; addisapproved by the examiner (s			has (have) been	□ approved by the
. The proposed drawing correction, filed				
Acknowledgement is made of the claim for pric	orlty under 35 U.S.C.	119. The ; filed on _	certified copy has been r	eceived not been received
Since this application apppears to be in condit accordance with the practice under Ex parte C	ion for allowance exce luayle, 1935 C.D. 11;	ept for form 453 O.G. 2	nal matters, prosecution as to 213.	the merits is closed in
I. Cther				
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Claims 3-5, 7, 10, 21 and 22 are pending.

Claims 3-5, 7, 10, 21 and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following reason applies"

"A compound which----or an antivirally active metabolite or residue thereof" is unclear. The specification does not provide any guidance. Prodrug is generally defined as a derivative of a parent drug which is converted in vivo (by way of many different chemical processes) into active, parent drug, the choice of such derivative (i.e. the prodrug) will vary from drug to drug since the function of prodrugs is to improve the pharmokinetics of the active form (e.g. solubility, prevention of drug loss before the receptor site is reached) and thus the choice of a suitable prodrug will be a function of the molecular structure of the active form, as well as the desired intended effect. specification provides no guidance as to what constitutes suitable prodrug(s) "a salt, ester, or salt or an ester" remains unclear. The specification does not provide any quidance.

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claims 3-5, 7, 10, 21 and 22 are rejected under 35 USC 103 and 102 over US '466. Applicant's urges that one of ordinary skill would expect the "nonnatural" nucleoside analogue to have little or no activity. It is well known in the antiviral art that any small change may significantly affect the activity. Attention is also invited to Chang et al article of record. Since compound disclosed there has four possible stereoisomers, all four of them were tested to find out which one is responsible for the activity and cytotoxicity. Thus, it is a routine for one skilled in the art to test all possible stereoisomers of an active compound.

As discussed in previous action, US '466 teaches how to prepare BCH-189 or BCH-189 analogs that are enantiomerically-enriched. The choice of the enzyme that is selective for the desired enantiomer (or selective for the undesired enantiomer, as a method of eliminating it) is within the skill of the art. The patent teaches how to prepare enantiomerically-enriched BCH-189 and analogs thereof. The figures, schemes and formulas are not required to reflect the configuration.

Rejection over US '407 remains for the reasons of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED

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STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

A facsimile center has been established in Group 1200, room 3C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (7030 308-455 or 305-3592.

Any inquiry concerning this communication should be directed to Examiner Tsang at telephone number (703) 308-4715.

e Tout

TSANG: jd PRIMARY EXAMINER
May 19, 1994 GROUP 1200